

9.0 UNCERTAINTIES

The following sections will describe how uncertainties that will be introduced into the HHRA will be evaluated. Uncertainty is inherent in the risk assessment process even when the most accurate data are used. Section 9.1 discusses uncertainty and limitations in the HHRA process. Section 9.2 discusses qualitative uncertainty in the HHRA. Section 9.3 describes quantitative uncertainty in the HHRA. Lastly, Section 9.4 describes how uncertainty will be discussed in the HHRA.

9.1 UNCERTAINTY AND LIMITATIONS OF THE HUMAN HEALTH RISK ASSESSMENT PROCESS

The methods described in this protocol and the results of the HHRA are based on a combination of variables yielding exposure and, consequently, risk estimates that fall at an unknown percentile of the actual distributions of each. The degree of conservatism in the risk estimates, based on actual site-specific exposure, cannot be known; however, it is known that the protocol combines many conservative assumptions and is likely to overstate actual risk, thereby providing a margin of protection (U.S. EPA 1998a). The HHRA will analyze the degree of conservatism introduced into the assessment of exposure and risk.

9.2 TYPES OF UNCERTAINTY

This section discusses the types of uncertainty and the areas in which uncertainty could be introduced into the health risk assessment. Four basic types of uncertainty will be discussed in the HHRA:

(1) variable uncertainty, (2) model uncertainty, (3) decision-rule uncertainty, and (4) variability.

Variable uncertainty occurs when variables used in equations cannot be measured precisely or accurately.

Model uncertainty is associated with all phases of the risk assessment process including (1) animal models used as surrogates for testing human carcinogenicity, (2) dose-response models used in extrapolations, and (3) the computer models used to predict the fate and transport of chemicals in the environment (the ISCST3 air dispersion model).

Decision-rule uncertainty is introduced into the risk assessment in order to balance different social concerns when determining an acceptable level of risk. One of the most important aspects for the risk estimates, and the area of the assessment that may introduce the most decision rule uncertainty, is the selection of COPCs. The COPCs identified for the HHRA include compounds that have the potential to pose the greatest risk to human health through indirect exposure routes, such as the consumption of contaminated food. Another area of decision-rule uncertainty is the use of U.S. EPA-recommended default values including body weights, consumption rates, and lifespans. Inhalation and consumption rates are highly correlated to body weights for adults using a single point estimate for these variables instead of a joint probability distribution, which ignores a variability that may influence the results by a factor of two or three.

9.3 METHODS FOR DETERMINING QUALITATIVE UNCERTAINTY

In most cases, uncertainty can be identified but not quantified. This type of uncertainty occurs when a factor is known or expected to be variable but no data is available, such as when a COPC has no toxicity value or when estimating the exposure time of people at a specific site. In these cases, there may be default values available, or there may be no data available at all. Discussion about qualitative uncertainty will include an evaluation of the possible direction and orders of magnitude of the potential error.

9.4 METHODS FOR DETERMINING QUANTITATIVE UNCERTAINTY

Knowledge of experimental or measurement errors can also be used to introduce a degree of quantitative information into a qualitative presentation of uncertainty. In many cases, uncertainty associated with particular variable values or estimated risks can be expressed quantitatively and further evaluated with variations of sensitivity analyses.

When a detailed quantitative treatment of uncertainty is required, statistical methods will be employed. Two approaches to a statistical treatment of uncertainty with regard to variable values can be used. The first is to use an appropriate statistic to express all variables for which uncertainty is a major concern. For example, if a value used is from a sample (such as yearly emissions from a stack), the mean and standard deviation should both be presented. If the sample size is very small, it may be appropriate to (1) give the range of sample values and use a midpoint as a best estimate in the model, or (2) use the smallest and largest measured values to obtain two estimates that bound the expected true value.

Selecting the appropriate statistic depends on the amount of data available and the degree of detail required.

A second approach is to use the probability distributions of major variables to propagate variable value uncertainties through the equations used in a risk analysis. A probability distribution of expected values is then developed for each variable value. These probability distributions are typically expressed as either probability density functions (PDF) or cumulative probability density functions (CPF). The PDF presents the relative probability for discrete variable values, whereas the CPF presents the cumulative probability that a value is less than or equal to a specific value.

9.5 RISK ASSESSMENT UNCERTAINTY SECTION

The uncertainty, both qualitative and quantitative, associated with each phase of the HHRA will be evaluated. In cases where uncertainty can only be estimated qualitatively, the possible direction (overestimation or underestimation) and the orders of magnitude of the potential error will be presented. Quantitative uncertainty will be measured using the appropriate statistical methods and will be presented in the HHRA. In addition to common types of uncertainties mentioned in the sections above, uncertainty within the following specific areas of the HHRA will be discussed:

- Scaling factors based on JACADS trial burn data used to estimate TOCDF emissions while burning munitions with VX and HD
- Default parameter values used in the air dispersion modeling, media concentration estimation, exposure assessment, and risk characterization.
- Specific areas of uncertainty for each emission source (including the lack of trial burn data, waste feed rates, stack gas flow rates, etc.).